PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: NOTIFICATION OF TRANSMITTAL OF Cullen & Co INTERNATIONAL PRELIMINARY **GPO Box 1074** REPORT ON PATENTABILITY **BRISBANE OLD 4001** (Chapter II of the Patent Cooperation Treaty) (PCT Rule 71.1) Date of mailing 3 1 MAR 2006 (day/month/year) Applicant's or agent's file reference IMPORTANT NOTIFICATION 031392PC/KF Priority date (day/month/year) International filing date (day/month/year) International application No. PCT/AU2004/001800 21 December 2004 23 December 2003 Applicant

PROGEN INDUSTRIES LIMITED et al

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.
- 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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PATENT COOPERATION TREATY PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 031392PC/KF	FOR FURTHER AC	CTION	See Form PCT/IPEA/416		
International application No. PCT/AU2004/001800	International filing da 21 December 2004	te (day/month/year)	Priority date (day/month/year) 23 December 2003		
International Patent Classification (IPC) or national classification and IPC Int. Cl. C07H 5/10 (2006.01) A61P 7/00 (2006.01) A61P 43/00 (2006.01)					
		· · · · · · · · · · · · · · · · · · ·	(continued in Supplemental Box)		
Applicant PROGEN INDUSTRIES LIMITED et al					
This report is the international prelimina Authority under Article 35 and transmitt			mational Preliminary Examining		
2. This REPORT consists of a total of 7	sheets, including this c	over sheet.			
3. This report is also accompanied by ANN	NEXES, comprising:				
a. X (sent to the applicant and to the	International Bureau)	a total of 5 sheets, as	follows:		
sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).					
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.					
b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).					
4. This report contains indications relating	to the following items	:			
X Box No. I Basis of the repor	t		·		
Box No. II Priority			·		
X Box No. III Non-establishmer	nt of opinion with regar	d to novelty, inventive	step and industrial applicability		
Box No. IV Lack of unity of it	nvention		· · · · · · · · · · · · · · · · · · ·		
X Box No. V Reasoned stateme citations and expl	ent under Article 35(2) anations supporting su	with regard to novelty,	inventive step or industrial applicability;		
Box No. VI Certain document	ts cited				
Box No. VII Certain defects in	the international appli	cation			
Box No. VIII Certain observation	ons on the international	application			
Date of submission of the demand		Date of completion of	this report		
6 June 2005		24 March 2006			
Name and mailing address of the IPEA/AU		Authorized Officer-	1 0		
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929		O.L. CHAI Telephone No. (02) 62	La OLie 283		

Form PCT/IPEA/409 (Cover sheet) (April 2005)

International application No. **PCT/AU2004/001800**

Box	No.	Basis of	the report	
1.	Witl	n regard to the lan	guage, this report is based on:	
	X	The internationa	l application in the language in which it was filed	
			the international application into shed for the purposes of:	, which is the language of a
		internatio	nal search (under Rules 12.3(a) and 23.1 (b))	
		publication	on of the international application (under Rule 12.4(a))	·
		internation	nal preliminary examination (Rules 55.2(a) and/or 55.3(a))	
2.	furn	ished to the receiv I" and are not ann	ments of the international application, this report is based on (replaceme ving Office in response to an invitation under Article 14 are referred to it exed to this report): application as originally filed/furnished	
	$\overline{\mathbf{x}}$	the description:	•	
r" s	لتتنا	•	pages 1-2, 5-50 as originally filed/furnished	
()			pages* 3, 4 received by this Authority on 17 February 2006 with pages* received by this Authority on with the letter of	the letter of 17 February 2006
	X	the claims:		
			pages as originally filed/furnished pages* as amended (together with any statement) under Article 19	
			pages* 51-53 received by this Authority on 17 February 2006 with t	the letter of 17 February 2006
			pages* received by this Authority on with the letter of	
		the drawings:		•
			pages as originally filed/furnished	·
		•	pages* received by this Authority on with the letter of pages* received by this Authority on with the letter of	·
	\Box			aa T istima
,	=		g and/or any related table(s) - see Supplemental Box Relating to Sequence	ce Listing.
3.	Ш	The amendments	s have resulted in the cancellation of:	
7 X		٠ لـــا	ription, pages	•
		the clair	ms, Nos.	•
		the drav	wings, sheets/figs	
	ė	the sequ	nence listing (specify):	٠
		any tab	e(s) related to the sequence listing (specify):	
4.	X		been established as if (some of) the amendments annexed to this report are have been considered to go beyond the disclosure as filed, as indicated	
		the desc	ription, pages	
		X the clair	ms, Nos. 7-8	
		the drav	vings, sheets/figs	• •
		the sequ	nence listing (specify):	
		any tab	e(s) related to the sequence listing (specify):	
*	If i	tem 4 applies, some	or all of those sheets may be marked "superseded."	

International application No. PCT/AU2004/001800

Bo	No.	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
1.		uestions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be trially applicable have not been examined in respect of:
		the entire international application
	X	claims Nos: 1, 3 (in part)
	beca	use:
		the said international application, or the said claims Nos.
		relate to the following subject matter which does not require an international preliminary examination (specify):
	•	
\tilde{C}		the description, claims or drawings (indicate particular elements below) or said claims Nos.
		are so unclear that no meaningful opinion could be formed (specify):
		···
		And the state of t
		the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (specify)
		, , , , , , , , , , , , , , , , , , ,
	X	no international search report has been established for said claim Nos. 1, 3 (in part)
		A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
()		Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
		Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
		Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.
		A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it
		the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
		See Supplemental Box for further details.

International application No. PCT/AU2004/001800

Box No. V	Reasoned statement un citations and explanation	der Article 35(2) with regard to novelty, inventive ons supporting such statement	step or industrial applicability;
1. Statement			
No	velty (N)	Claims 1-6, 9-16	YES
		Claims	NO
Inv	ventive step (IS)	Claims 1-6, 9-16	YES
		Claims	NO ·
Ind	lustrial applicability (IA)	Claims 1-6, 9-16	YES
		Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this opinion:

- D1 WO 1985/000973
- D2 US 4459293
- D3 WO 2003/038054
- D4 Derwent Abstract Accession No 2000-100762/09
- D5 Derwent Abstract Accession No 2001-337999/36
- D6 Derwent Abstract Accession No 2000-116716/10
- D7 WO 1993/024506
- D8 WO 1997/018222
- D9 Derwent Abstract Accession No 96-116981/12
- D10 US 5700918
- D11 Chemical Abstracts AN 140:314439
- D12 Chemical Abstracts AN 141:54554
- D13 Chemical Abstracts AN 138:82903
- D14 Chemical Abstracts AN 133:267051
- D15 Chemical Abstracts AN 131:322848
- D16 Chemical Abstracts AN 129:107414

D11 and D12 are published after the priority date of the application. These documents may become relevant if the priority date of the application is found to be invalid at a later date.

Novelty (N) & Inventive Step (IS)

D1 discloses substituted phenyl-1-thio(poly-O-sulfo)- α (or β)-D-glucopyranosides, cation salts thereof and their use as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes.

D2 discloses bis- $[\beta$ -D-glucopyranosyl-1-thio (or sulfinyl or sulconyl)-arylene sulfate derivatives, the cation salts thereof, useful as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes.

D4 discloses sulfated galactose compounds (I) and their pharmaceutical preparation.

(continued in Supplemental Box)

International application No. PCT/AU2004/001800

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: International Patent Classification (IPC)

Int. Cl.

 A61K 31/70 (2006.01)
 A61P 7/02 (2006.01)
 C07H 11/04 (2006.01)

 A61K 31/7012 (2006.01)
 A61P 29/00 (2006.01)
 C07H 13/12 (2006.01)

 A61K 31/7016 (2006.01)
 A61P 31/00 (2006.01)
 C07H 15/04 (2006.01)

 A61K 31/7028 (2006.01)
 A61P 35/00 (2006.01)
 C07H 15/18 (2006.01)

Action Date: 24 March 2006

International application No. PCT/AU2004/001800

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: item 4 of Box No. I

The subject matter of claims 7-8 goes beyond the disclosure in the international application as filed. Substituting one or more sulfate groups of the compounds of claim 1 with an alternative charged group would introduce new matter into the application. The report is established as if such amendment had not been made.

International application No. PCT/AU2004/001800

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

D5 discloses glucopyranose derivatives of formula (1) useful in the prevention and/or treatment of HIV infections, asthma, atopic dermatitis, and allergic and inflammatory disorders.

D6 discloses glucopyranose derivatives of formulae (I) useful in the treatment of HIV.

D7 discloses glucopyranose or galactopyranosy derivatives of formula I or II (gluand their use in modulating cell mediated immune responses eg for treating psoriasis, asthma, inducing tolerance to antigens.

D8 discloses glucopyranose or galactopyranosy derivatives of formulae I and II with immunosuppressive and tolerogenic activity for modulating cell mediated immune responses especially inflammation eg for treating psoriasis, asthma, dermatitis.

discloses mono- or di- saccharide derivatives with galato or gluco stereochemistry.

D13 discloses a galactopyranosyl derivative as a pharmaceutical.

D14 discloses a galactopyranosyl derivative with anti-HIV activity.

D15 discloses a galactopyranosyl derivative with anti-inflammatory activity.

D16 discloses a galactopyranosyl derivative with anti-inflammatory activity.

The proviso in claim 1 excludes the stereochemistry of I to be a gluco or galacto, therefore D1, D2, D4-D9 and D13-D16 no longer anticipate the claims.

D10 discloses a moranoline derivative of formula (I) used for treating inflammation, immunopathy, viral infection and cancer. Claim 1 as amended is restricted to oxygen as the heteroatom in the ring of formula I. Therefore D10 no longer anticipates the claims.

D3 discloses compounds of Structures I-VI (see Figures 8-11) which no longer anticipate the amended claim 1.

In summary, none of D1-D10 and D13-D16 discloses all of the features of each of the independent claims. Therefore of the claims are novel and meet the requirements of Article 33(2) PCT with regards to novelty. The subject matter of these claims is also considered not obvious and meets the requirements of Article 33(3) PCT with regards to inventive step.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

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